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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,168	12/08/2000	William H. Frey II	1670.002 (5784-54)	2361

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/733,168

Applicant(s)

FREY, WILLIAM H.

Examiner

Janet L Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-31, drawn to a method of administering a cytokine to the central nervous system, classified in class 514, subclass 2.
- II. Claims 32-60, drawn to a method of administering a cytokine to the lymphatic system, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

The methods are distinct from each other because they require administration to different sites.

Thus they have different goals and different outcome measures, and the searches required for each are not coextensive.

Because these inventions are distinct for the reasons given above and the search required for Group I is different from that required for Group II, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

For Invention I, there are four groups of species:

1. Site of administration:
 - a. Nasal cavity
 - b. Conjunctiva
 - c. Oral tissue

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d. Skin

Each of these sites of administration has different considerations and a different status in the art. Success with one would not render success with another obvious.

2. Cytokine

a. IFN- α

b. IFN- β

c. IFN- γ

These are different cytokines with different pharmacological properties that are used to treat different conditions. Success with one would not render success with another obvious.

3. Site of action

a. Cerebellum

b. Superior colliculus

c. Periventricular white matter

d. Optic nerve

e. Midbrain

f. Pons

g. Olfactory bulb

h. Anterior olfactory nucleus

i. Spinal cord

j. Brain stem

k. Cortical structure

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1. Subcortical structure

Each of these sites has different considerations and a different status in the art, and would be useful for different diseases. Success with one would not render success with another obvious.

4. Disease

- a. Viral meningitis
- b. Herpes simples
- c. Hepatitis C
- d. HIV
- e. Alzheimer's disease
- f. Primary Sjorgen's Syndrome
- g. Multiple sclerosis
- h. Glioma

These are different diseases with different causes, different courses, and different effects. Successful treatment of one would not render successful treatment of another obvious.

If Invention I is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each group for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 6, 12, 14, 15, 19, 20, 24, and 30 are generic.

For Invention II, there are four groups of species:

- 1. Site of administration:
 - a. Nasal cavity

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b. Conjunctiva

c. Oral tissue

d. Skin

Each of these sites of administration has different considerations and a different status in the art. Success with one would not render success with another obvious.

2. Cytokine

a. IFN- α

b. IFN- β

c. IFN- γ

These are different cytokines with different pharmacological properties that are used to treat different conditions. Success with one would not render success with another obvious.

3. Site of action

a. Deep cervical node

b. Superficial cervical node

Each of these sites has different considerations and a different status in the art, and would be useful for different diseases. Success with one would not render success with another obvious.

4. Disease

a. Viral meningitis

b. Herpes simplex

c. Hepatitis C

- d. HIV
- e. Alzheimer's disease
- f. Primary Sjorgen's Syndrome
- g. Multiple sclerosis
- h. Glioma

These are different diseases with different causes, different courses, and different effects. Successful treatment of one would not render successful treatment of another obvious.

If Invention I is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each group for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 32, 33, 37, 42, 44, 45, 49, 53, and 55 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.

December 17, 2001

Yvonne Eyler
YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600